

REMARKS

This amendment is responsive to the final Office Action mailed January 27, 2006 (hereafter "Office Action"). The currently pending claims in this application are 25, 27, 29-32, 34-41, 43, 44, 46-52, and 54-59. Claims 25, 41, and 54 are independent. Reconsideration and allowance of all pending claims is respectfully requested in view of the remarks following below.

Claims 25, 27, 29-32, 34-41, 43, 44, 46-52, and 54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,200,347 to Anderson et al. ("Anderson") in view of U.S. Patent 5,624,463 to Stone et al. ("Stone"). These rejections are respectfully traversed for the reasons presented herein, and the same reasons presented in Applicants' preceding Amendment and Response filed on December 7, 2005, which remain applicable and are incorporated herein in by reference.

Independent claim 25 requires *inter alia* "a body with first and second ends and a plurality of through-holes extending between the ends" and "a first and second cortical end cap disposed respectively on each end of the body, at least one of the end caps comprising a height and a plurality of recesses each defining: a wall surface extending along the height of the cap, a depth that is less than the height of the cap, and a bearing surface disposed at an angle to the wall surface." Claim 25 further requires "a plurality of cortical struts...wherein each cortical strut is disposed in one of the through holes of the body and received in one of the recesses so that the strut bears against at least a portion of the bearing surface in the recess." The underlined limitations are not taught or fairly suggested by Anderson or Stone, either alone or in combination.

The Office Action states that Anderson discloses "two cortical end caps (70) having receiving regions, and a plurality of cortical struts (7). The receiving regions are the plurality of holes (5), the bearing surface is the surface created at each hole along the thickness of each cortical cap and the end part is the part created at the rim top surface of each hole cap." (Office Action, p. 2) (emphasis added.) Claim 25 was previously amended to clarify the invention and recite "a bearing surface disposed at an angle to the wall surface;" the wall surface being defined by claim 25 as "extending along the height of the cap." The Office Action recites that the "bearing surface" in Anderson as defined by the Examiner does not describe all limitations of

claim 25. This is because Anderson's end caps are bored completely through (*see* Anderson, FIG. 11B). As Applicants have already explained in the prior Office Action response, there simply is no bearing surface at an angle to the wall surface of the recess as required by claim 25. Further, Anderson does not disclose that the "strut bears against at least a portion of the bearing surface" as claimed. Nor does Anderson disclose a recess in the cap having "a depth that is less than the height of the cap." (*See*, for example, Applicants' FIG. 16).

In sum, Applicant's claimed invention is clearly distinguishable from Anderson which does not teach or suggest the foregoing limitations of claim 25.

Independent claims 41 and 54 are similar to claim 25. Claims 25, 41, and 54 all require an end cap having a recess with a depth less than the height or thickness of the cap. Claims 41 and 54 similarly clarify the bearing surface and struts as follows. Claim 41 requires "a bearing surface disposed in the recess and oriented at an angle to the height of the end cap" and the strut engaging at least a portion of the bearing surface. Claim 54 requires a first and second end cap each having a recess defining a bearing surface disposed at an angle to the longitudinal axis extending between the top surface and the bottom surface of the end caps, and the strut engaging at least a portion of the first and second bearing surfaces. Anderson does not teach or fairly suggest an implant as required by claims 41 and 54, for at least the same reasons as claim 25 discussed above. Accordingly, these claims are also clearly distinguishable from Anderson.

The Office Action concedes the shortcomings of Anderson, noting that "Anderson et al. also does not disclose a blind bore in the cortical end caps (70) for the purpose of connecting two pieces together." (Office Action, p. 2). Relying on Stone, the Office Action states without explanation or factual support that "[i]t would have been obvious at the time the invention was made to modify the cortical end caps of the Anderson et al reference with the blind bore end caps of Stone et al. in order to connect two pieces together" (referring to FIG. 9). (Office Action, pp. 2-3.) (emphasis added.) Applicants respectfully traverse this rejection for several reasons.

First, Stone does not make up the deficiencies of Anderson with regards to providing the missing elements of independent claims 25, 41, and 54. Referring to FIG. 9, Stone discloses a prosthetic articular knee cartilage having a conical base 20 that is implanted into bone 450 and a solid cylindrical disk-shaped matrix 12 that is affixed to the base. Matrix 12 is made of biocompatible and bioresorbable fibers and polysaccharide. (Stone, Col. 3, lines 17-32.) Base

20 is made of metal, plastic, or resorbable materials. (Stone, Col. 9, lines 26-35.) Neither structure is made of cortical or cancellous bone, and of these two structures, only base 20 has apertures or bores. Assuming the Examiner considers the conical base to be the “blind bore end caps” as stated in the Office Action, Applicants’ claimed invention is still readily distinguishable. Stone does not teach or suggest a body with a plurality of through-holes, cortical struts, cortical end caps with recesses, or cortical struts received in the cortical end cap recesses as all required by claims 25, 41, and 54. Although Stone may disclose blind bores, Stone does not explicitly teach or suggest providing a cortical end cap with partial-depth recesses having a bearing surface disposed at an angle to the wall of the recess. Thus, even if one were to combine the teachings of Stone and Anderson, the spinal implant with its elements recited in claims 25, 41, and 54 would still not result. Such an arrangement would not be made without the hindsight knowledge of the Applicants’ own teachings being used against itself, which is an improper basis for obviousness. *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1553 (Fed. Cir. 1983).

Since Stone does not disclose a cortical end cap having partial recesses or blind bores, there must be some suggestion in the first place to even modify the end caps of Anderson to include the blind bores of Stone. “The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” MPEP 706.02(j) (citing *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)).

In this case, there is no suggestion or motivation to combine Anderson and Stone. Indeed, the Office Action does not state any factual basis or line of reasoning for making the combination. The Examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in factual basis. *In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967).

Anderson and Stone are directed to two different areas of medical treatment, each having their own unique technical considerations and problems. Applicants' invention and Anderson generally relate to spinal implants. By contrast, Stone is directed to a prosthetic knee-joint cartilage and in vivo scaffold for regeneration of articular cartilagenous tissue. (Stone, Col. 1, lines 19-23.) Indeed, the objective of Stone is to fill the need for "an improved prosthetic scaffold for articular cartilage which is biocompatible, soft, lubricating, and durable." (Stone, Col. 2, lines 42-44.) Accordingly, Stone does not discuss or acknowledge the problem of transmitting high compressive spinal loads from vertebrae-to-vertebrae through a lower strength, albeit more osteoconductive cancellous body using cortical end caps and cortical struts. Therefore, there would be no basis to combine Stone with Anderson for at least this reason.

Furthermore, there is no suggestion or motivation to combine Anderson and Stone for the additional reason that Stone does not disclose any load-bearing function associated with its blind bores whatsoever, much less the benefits associated with providing an angled load bearing surface in a cortical end cap recess that engages a cortical strut as provided by Applicant's claimed invention. In Stone, base 20 is formed in a piston compression mold shown in FIG. 6, which leaves so-called blind bores or holes 126 in the finished base as shown in FIGS. 4B & 7. (Stone, Col. 9, lines 36-60.) The mold is then opened and fibers for matrix disk 12 are painted across the entire top of base 20 covering over holes 126 therein. (Stone, Col. 9, lines 61-64.) Base 20 is then reinserted into the piston mold "so that the fibers painted on the top surface of the base component 20 are compressed. As the compression occurs, some of the fibers are forced into the holes 126 in the top of the base component." (Stone, Col. 9, line 66-Col. 10, line 2.) The composite base 20 and matrix 12 element are then dried to fuse the components together. (Stone, Col. 10, lines 2-7.)

Stone thus teaches that some of the fibers making up matrix 12 are forced into holes 126 during fabrication as merely a means to secure the matrix disk to the conical base 20. Therefore, the holes in Stone need only be deep enough to receive some fibers from matrix 12 for affixation to conical base 20. Accordingly, it is not surprising that Stone does not disclose or discuss any load-bearing function associated with these fibrous projections or blind bores in base 20. The mere fact that Stone may have blind bores without more does not provide the requisite suggestion or motivation to modify Anderson's end caps to include blind bores/holes or a load

bearing surface disposed at an angle to walls of the hole, as required by Applicants' claims 25, 41, and 54. Therefore, Stone also does not teach or suggest the desirability of modifying Anderson in the manner prescribed in the Office Action. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340 (Fed. Cir. 2000) (motivation to combine requires desirability of making the combination, not merely a trade-off).

Moreover, the "question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP 2141.02 (citing *Statoflex, Inc. v. Aeroquip Corp.* 713 F.2d 1530 (Fed. Cir. 1983) (emphasis in original). Considering the invention as whole, Applicants' implant structure recited in independent claim 25, 41, and 54 provides more uniform distribution of the compressive loads imposed on the implant by adjacent vertebrae than Anderson. The claimed invention eliminates the problem of pinpoint reactionary loads imparted back to the adjacent vertebrae by precluding direct contact with the struts (due to the force being distributed through the entire end cap) in contrast to Anderson, thereby reducing the probability of pinpoint vertebrae stress fractures. This creates a lower force/unit area on the existing vertebrae than Anderson. Also in contrast to Anderson, non-uniform compressive loads imposed on the implant by the spine are evenly distributed across the surface area of end cap normal to the load. This results in more equal loading of each cortical strut through the claimed recessed bearing surfaces in the end caps which are engaged by the struts, and ensures individual cortical struts are not overloaded to the point of failure. Although the Office Action again states that Applicant has not disclosed that a recess that does not extend completely through the end cap provides an advantage, Applicants respectfully disagree as noted in their previous Office Action response. Applicant's original application discloses that an advantage of the novel end cap recesses that do not extend completely through the cap unlike Anderson will "serve to distribute loadings on the implant." (*See Applicants' disclosure*, page 22, lines 11-12; *see also* FIG. 16.) The purpose and advantage of such an end cap as now claimed is not recognized, disclosed, or fairly suggested by Anderson or Stone. Indeed, neither Anderson, nor Stone provides such advantages as in Applicants' invention recited in claims 25, 41, and 54, that allows the use of a softer cancellous bone for spinal implants without imparting pinpoint reactionary loads on existing vertebrae on either side of the implant.

In view of the foregoing, the question arises as to why one skilled in the art would even modify the end caps of Anderson in the first place with the blind bores of Stone “in order to connect two pieces together” as stated in the Office Action. (Office Action, pp. 2-3.) Anderson’s end caps with bores extending completely through the caps to receive cortical struts appears to provide an entirely acceptable manner of connecting the cortical end caps with the cancellous intermediate body of the implant for the implant’s intended purpose. Without knowledge of the Applicant’s own teachings, one would not question the acceptability of Anderson’s method of connection nor recognize the undesirability of allowing the cortical struts to directly contact vertebrae adjacent to the spinal implant. As discussed herein, Stone provides no suggestion or motivation as why one skilled in the art would even attempt to modify the apparently acceptable end caps of Anderson. Accordingly, this is telling as to the nonobviousness of Applicants’ claimed invention. *See* MPEP 2143 (‘The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant’s disclosure.’) (citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991)).

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure.” MPEP 706.02(j) (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

In sum, for at least the reasons presented herein, the Office Action has failed to establish a *prima facie* case of obviousness because at least the first and third criteria noted above have not been met. Accordingly, independent claims 25, 41, and 54 are believed to be allowable.

Claims 27, 29-32, 34-40, 43, 44, 46-52, and 55-59 depend directly or indirectly from independent claims 25, 41, and 54. These claims are allowable based on the allowability of their

respective independent claims and the additional limitations added by these claims which further distinguish over the prior art. MPEP 2143.03 (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988)).

CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration and allowance of all pending claims. Should the Examiner disagree with the allowability of any of the claims, the Examiner is respectfully requested to kindly contact Applicants' undersigned representative at 212-309-6375 to resolve any remaining issues.

Respectfully submitted,

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